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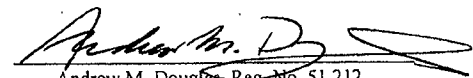
**APPEAL BRIEF**

Applicant : Zikorus et al.  
App. No : 09/825,741  
Filed : April 3, 2001  
For : METHOD AND APPARATUS FOR  
POSITIONING A CATHETER  
RELATIVE TO AN ANATOMICAL  
JUNCTION  
Examiner : Roy, Baisakhi  
Art Unit : 3737

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Commissioner for Patents

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Sir:

In accordance with the Notice of Appeal filed October 21, 2008, Appellants, Applicants  
in the above-referenced patent application, submit this Appeal Brief.

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#### **I. REAL PARTY IN INTEREST**

The real party in interest in the present application is VNUS Medical Technologies, Inc., the assignee of the present application.

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## **II. RELATED APPEALS AND INTERFERENCES**

No related appeals, interferences, or court proceedings are currently pending.

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### **III. STATUS OF CLAIMS**

Claims 1-7, 16, 21, 50-53, 70-72 and 75-94 are currently pending in the application and are the subject of this appeal. Claims 8-15, 17-20, 22-49, 54-69 and 73-74 were previously cancelled. All of the pending claims were rejected in the Final Office Action having a notification date of July 23, 2008 (hereinafter "Final Office Action"). The pending claims are listed in Appendix I.

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#### **IV. STATUS OF AMENDMENTS**

No amendments are made in response to the Final Office Action.

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## V. SUMMARY OF CLAIMED SUBJECT MATTER

The present application includes four independent claims. Each independent claim is summarized below, with citations to corresponding portions of the specification and drawings of the application as filed as required by 37 C.F.R. § 41.37(c)(1)(v). Certain dependent claims are also summarized below with citations to corresponding portions of the specification and drawings. These citations are set forth to illustrate specific examples and embodiments of the recited claim language and not to limit the claims.

### Claim 1

Claim 1 is directed to a method of positioning an elongate treatment device proximate to a junction in a hollow anatomical structure of a patient. The method includes at least the following:

- introducing the treatment device into the hollow anatomical structure, the treatment device comprising an elongate shaft and an electrically driven energy application device at a working end of the shaft (*see, e.g.*, p.7 ll.5-27; p.9, l.10-p.10, l.8; p.11, l.21-p.12, l.3; and FIG. 4 elements 36 and 56);
- identifying the junction in the hollow anatomical structure by emitting light via a fiber optic device positioned in the hollow anatomical structure (*see, e.g.*, p.8, l.27-p.9, l.15; p.10, ll.9-19; and FIGS. 3 and 7);
- positioning the working end of the treatment device proximate the junction identified in the step of identifying (*see, e.g.*, p.9, l.16-p.10, l.8; and FIG. 9);
- applying energy to the hollow anatomical structure proximate the junction via the energy application device so as to lead to a reduced diameter for the hollow anatomical structure (*see, e.g.*, p.7, ll.5-27; p.8, ll.12-26; p.9, ll.21-24; and FIG. 9).

### Dependent Claim 5

Claim 5 recites method of Claim 3 further including the step of measuring the length of the fiber optic device introduced into the patient until the attribute of the light changes (*see, e.g.*, p.9, ll.16-24). Claim 3 depends from Claim 1 and recites wherein an attribute of the light

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changes upon the fiber optic device reaching the junction of the hollow anatomical structure (*see, e.g., p.9, ll.10-15*).

#### Dependent Claim 6

Claim 6 recites the method of Claim 5 further including the step of removing the fiber optic device after the step of measuring (*see, e.g., p.9, ll.16-24*). Claim 5 depends from Claim 3 which depends from Claim 1 as discussed above.

#### Dependent Claim 7

Claim 7 recites the method of Claim 5 wherein the step of positioning further includes the step of inserting the treatment device for the same length as measured in the step of measuring the length of the fiber optic device (*see, e.g., p.9, ll.16-24*). Claim 5 depends from Claim 3 which depends from Claim 1 as discussed above.

#### Dependent Claim 16

Claim 16 recites the method of Claim 1 wherein the step of introducing said treatment device comprises introducing said treatment device over a guidewire with a hook shaped tip located at the distal end of a guide wire (*see, e.g., p.9, l.25-p.10, l.19; p.11, l.21-p.12, l.3; p.12, l.27-p.13, l.8; p.13, ll.4-30; and FIG. 8*), and the hook shaped tip is adaptable to engage the junction of the hollow anatomical structure while the treatment device travels over the guidewire to the junction (*see, e.g., p.12, l.27-p.13, l.8; p.13, ll.16-30; and FIG. 8*).

#### Claim 50

Claim 50 is directed to a method of positioning a catheter within a hollow anatomical structure. The method includes at least the following:

- introducing a guide wire having a hook-shaped tip into the hollow anatomical structure (*see, e.g., p.9, l.25-p.10, l.19; p.12, l.27-p.13, l.8; p.13, ll.16-30; and FIG. 8*);



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- hooking the hook-shaped tip of the guide wire to an ostium of a junction within the hollow anatomical structure (*see, e.g.*, p.12, l.27-p.13, l.8; p.13, ll.16-30; and FIG. 8);
- introducing a catheter having a working end into the hollow anatomical structure over the guide wire (*see, e.g.*, p.9, l.25-p.10, l.19; p.11, l.21-p.12, l.3; p.13, ll.4-30);
- positioning the working end of the catheter proximate the junction identified in the step of hooking (*see, e.g.*, p.9, l.25-p.10, l.19; p.13, ll.4-30); and
- applying energy to the hollow anatomical structure at the treatment site via an energy application device at the working end of the catheter to heat but not cut the hollow anatomical structure until the hollow anatomical structure durably assumes a smaller size such that the reduced diameter of the hollow anatomical structure effectively ligates the hollow anatomical structure (*see, e.g.*, p.7, ll.5-27; p.8, ll.12-26; p.9, ll.21-24; and FIG. 9).

#### Dependent Claim 52

Claim 52 recites the method of Claim 50 wherein the step of positioning further includes the step of stopping the advancement of the catheter by a mechanical stop located proximal to the hook shaped tip of the guide wire (*see, e.g.*, p.13, ll.9-15).

#### Dependent Claim 53

Claim 53 recites the method of Claim 50 further comprising the step of measuring the length of the guide wire introduced into the patient in the step of hooking (*see, e.g.*, p.9, ll.16-24).

#### Claim 78

Claim 78 is directed to a method of positioning a device for application of therapeutic energy to a target portion of a hollow anatomical structure. The method includes at least the following:

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- emitting light from within a hollow anatomical structure (*see, e.g.*, p.8, l. 27-p.9, l. 15; p.10, ll.9-19; and FIGS. 3 and 7);
- monitoring the light from outside the hollow anatomical structure to determine information about the location of a junction between a target portion and a region adjacent the hollow anatomical structure (*see, e.g.*, p.8, l. 27-p.9, l. 15; p.10, ll.9-19; and FIGS. 3 and 7);
- introducing a catheter having a working end into the hollow anatomical structure, the catheter having a therapeutic energy device at the working end, the therapeutic energy device distinct from the light (*see, e.g.*, p.9, l.16-p.10, l.8; and FIG. 9);
- using the information to position the therapeutic energy device near the junction (*see, e.g.*, p.9, l.16-p.10, l.8; and FIG. 9); and
- applying energy from the therapeutic energy device to the target portion (*see, e.g.*, p. 7, ll.4-27; p.8, ll.12-26; p.9, ll.21-24; and FIG. 9).

#### Claim 89

Claim 89 is directed to a method of positioning a device for application of therapeutic energy to a target portion of a hollow anatomical structure. The method includes at least the following:

- emitting visual feedback light from a visual feedback device positioned within a hollow anatomical structure (*see, e.g.*, p.8, l. 27-p.9, l. 15; p.10, ll.9-19; and FIGS. 3 and 7);
- monitoring the visual feedback light from outside the hollow anatomical structure to determine information about the location of a junction between a target portion and a non-target portion of the hollow anatomical structure (*see, e.g.*, p.8, l. 27-p.9, l. 15; p.10, ll.9-19; and FIGS. 3 and 7);
- introducing, into the hollow anatomical structure, a catheter having a therapeutic energy device at the catheter's working end, the therapeutic energy device distinct from the visual feedback device (*see, e.g.*, p.9, l.16-p.10, l.8; and FIG. 9);

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- using the information to position the therapeutic energy device near the junction and prevent the therapeutic energy device from extending into the non-target portion (*see, e.g., p.9, l.16-p.10, l.8; and FIG. 9*); and
- applying energy from the therapeutic energy device to the target portion (*see, e.g., p. 7, ll.4-27; p.8, ll.12-26; p.9, ll.21-24; and FIG. 9*).

To the extent that Appellants decline to present argument herein with respect to some of the pending dependent claims, Appellants do not imply that the limitations added by such dependent claims are disclosed or suggested by the references relied upon in the Final Office Action.

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## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

As the grounds of rejection for review:

1. Whether Claims 1-4, 21, 70-72 and 75-94 are unpatentable under 35 U.S.C. § 103(a) over Cohen et al. (U. S. Pat. No. 5,556,396, hereinafter "Cohen"), in view of Navarro et al. (U. S. Pat. No. 6,398,777, hereinafter "Navarro")?
2. Whether Claim 5 is unpatentable under 35 U.S.C. § 103(a) over Cohen, in view of Navarro?
3. Whether Claim 6 is unpatentable under 35 U.S.C. § 103(a) over Cohen, in view of Navarro?
4. Whether Claim 7 is unpatentable under 35 U.S.C. § 103(a) over Cohen, in view of Navarro?
5. Whether Claim 16 is unpatentable under 35 U.S.C. § 103(a) over Cohen, in view of Navarro?
6. Whether Claims 50-51 are unpatentable under 35 U.S.C. § 103(a) over Cohen, in view of Navarro?
7. Whether Claim 52 is unpatentable under 35 U.S.C. § 103(a) over Cohen, in view of Navarro?
8. Whether Claim 53 is unpatentable under 35 U.S.C. § 103(a) over Cohen, in view of Navarro?

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## VII. ARGUMENT

### 1. The Obviousness Rejection Regarding Independent Claims 1, 78 and 89 is Incorrect.

#### **A. The Examiner's Asserted rejections Regarding Independent Claims 1, 78 and 89.**

The Final Office Action asserts that Cohen teaches a "method of electrically treating the sapheno-femoral junction by positioning a device for application of therapeutic energy to the anatomical structure," and that Cohen further includes a "feedback device for sensing a pre-selected parameter of the vessel."<sup>1</sup> However, position in a vessel is not a parameter of a vessel and, as discussed below, the "feedback device" of Cohen is actually a thermocouple or other electrical sensor and has nothing to do with positioning the device. The Final Office Action asserts that Navarro teaches "a method of positioning a catheter proximate to a junction in a hollow anatomical structure."<sup>2</sup> The Final Office Action argues that Navarro teaches "introducing a catheter into the hollow anatomical structure and identifying the junction based on feedback from the catheter with the use of light emitted from a fiber optic device."<sup>3</sup> Next, the Final Office Action asserts that Navarro teaches applying energy to the hollow anatomical structure to reduce the size of the structure.<sup>4</sup>

The Final Office Action states that it would be obvious to combine Cohen and Navarro. The assertion that this combination is proper appears to be based on: (1) A characterization of Cohen's teaching of electrical "feedback" (even though that feedback has nothing to do with positioning); and (2) the Examiner's assertion that Navarro teaches "visual guidance or feedback." Based on the Examiner's characterization of Cohen and Navarro, it is asserted that modifying Cohen to accommodate the visual feedback of Navarro is obvious.<sup>5</sup>

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<sup>1</sup> Final Office Action at p. 2.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* (citation omitted).

<sup>4</sup> *Id.* at 3.

<sup>5</sup> Applicants note that as the argument section of the Final Office Action includes only broad statements of what Cohen and Navarro teach without sufficient reference to particular claims or claim limitations, the rejection fails under 37 C.F.R. § 1.104(c) to particularly point out and explain the pertinence of each reference in regard to the rejected claims. Because of the vague

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### **B. Legal Requirements for Establishing a Showing of Obviousness**

The Examiner bears the initial burden to establish and support a *prima facie* case of obviousness.<sup>6</sup> To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art.<sup>7</sup> Additionally, to establish a *prima facie* case of obviousness, some reason to modify the reference must be provided by the Examiner, and that reason should be found either in the references or in the knowledge generally available to those of ordinary skill in the art.<sup>8</sup> To establish the *prima facie* case, the references must be considered in their entirety.<sup>9</sup> Considerations such as teachings away in the art and the possibility that modifying the reference will render the reference unsatisfactory for its intended purpose must also be considered.<sup>10</sup> Finally, even once a *prima facie* case of obviousness is established, it can still be rebutted if the claimed combination proceeds contrary to the accepted wisdom in the art.<sup>11</sup> Where the teachings of two or more prior art references conflict, the Examiner must weigh the

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rejections it is unknown whether the issues have been correctly identified and the Appellants have not been given fair opportunity to reply. See e.g. M.P.E.P. 706.02(j).

<sup>6</sup> See *In re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. 143 (C.C.P.A. 1976).

<sup>7</sup> See *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

<sup>8</sup> See *KSR International v. Teleflex*, 127 S.Ct. 1727 at 1741 (2007) ("it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."), see also, *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). "The references themselves, not the invention itself, must provide some teaching whereby the appellant's combination would have been obvious." *In re Forman*, 933 F.2d 982 (Fed. Cir. 1991); *Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*, 21 F.3d 1068 (Fed. Cir. 1993).

<sup>9</sup> See *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) and M.P.E.P. 2141.02 VI.

<sup>10</sup> *Id.*; Also see *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984) and M.P.E.P. 2143.01 V.

<sup>11</sup> The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 228 U.S.P.Q. 685 (Fed. Cir. 1986); *In re Geisler*, 116 F.3d 1465, 1471, 43 U.S.P.Q.2d 1362, 1366 (Fed. Cir. 1997); and *KSR International*, 127 S.Ct. 1727 at 1740 ("when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious").

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power of the references to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another.<sup>12</sup>

**C. The Final Office Action's Obviousness Rejection Is Legally Deficient.**

Appellants respectfully submit that the Final Office Action's grounds of rejection are insufficient for at least the following reasons: (a) the grounds of rejection and arguments do not take into account teachings away in the relevant art with respect to the claimed combination; (b) the grounds of rejection and arguments do not take into account the frustration of purpose of Cohen by the combination; (c) the grounds of rejection and arguments do not take into account the unlikelihood of success of the combination and (d) the reasons provided for the asserted combination are based on improper hindsight reasoning.

**a. It is Legal Error for the Examiner to Ignore Teachings Away in the Art**

The M.P.E.P. states: "[i]t is improper to combine references where the references teach away from their combination."<sup>13</sup> The Final Office Action improperly ignores clear teachings away from the presently claimed combination. In particular, Navarro criticizes other, non-laser modes of treatment and specifically disparages the use of electricity for resistive heating of a hollow anatomical structure. Navarro teaches away from use of electricity to treat varicose veins, stating that "use of electricity inevitably leads to coagulation of blood within the blood vessel, rather than causing fibrosis of the blood vessel itself."<sup>14</sup>

As noted above, the Final Office Action appears to be completely silent regarding the previously noted teachings away in the art of record. It is clear that the Final Office Action is not weighing the teachings of the art away from the claimed combination, as required by law.<sup>15</sup>

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<sup>12</sup> See *In re Young*, 927 F.2d 588, 18 U.S.P.Q.2d 1089 (Fed. Cir. 1991).

<sup>13</sup> M.P.E.P. § 2145(X)D2, citing *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983).

<sup>14</sup> Navarro at col. 2, ll. 1-6.

<sup>15</sup> See footnote 12 *supra* and accompanying text.

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Mere presence of a feature, with no reason to select it from among other options in the art, cannot rebut clear teachings away.<sup>16</sup>

In light of the Final Office Action's failure to meet the proper legal standard, and the presence of clear teachings away discussed herein, Appellants submit that, even if a *prima facie* case of obviousness had been established, it is rebutted by the clear teachings away in the art.

b. The Modification of Cohen as Proposed Would Render Cohen Unsatisfactory.

Modifying Cohen as suggested in the Final Office Action would render Cohen unsatisfactory for its intended purpose. Some of the purposes of the invention identified by Cohen include, for example, providing a flexible electrode device<sup>17</sup> and controlled heating of a vessel.<sup>18</sup>

Cohen teaches that the conductor device has an outside diameter of 0.018 inch and a narrower "bendable segment" with a diameter of 0.010 inch.<sup>19</sup> The end tip with the electrode can be slightly larger.<sup>20</sup> The fiber optic of Navarro is taught to be about .2-.6 microns, or 0.0079-0.024 inch in diameter.<sup>21</sup> Thus the fiber optic device of Navarro is larger or only slightly smaller than the bendable section of Cohen making it nearly impossible to incorporate the Navarro device into the Cohen device while maintaining the flexibility of the bendable segment. Cohen teaches that the bendable section is important to the invention to allow the device to properly navigate the veins and vein side branches in the body.<sup>22</sup> Not only would it be extremely difficult to insert a fiber optic within the Cohen device but whether within or connected along side, adding the fiber optic would necessarily make the Cohen catheter much more rigid, which is contrary to the intended purpose of Cohen.

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<sup>16</sup> *Id.* In making this argument, Appellants do not concede that any of the claimed features are actually present in the cited references, alone or in combination.

<sup>17</sup> Cohen at col. 5, ll. 5-11.

<sup>18</sup> *Id.* at ABSTRACT.

<sup>19</sup> *Id.* at FIG. 2 and col. 5, ll. 1-11.

<sup>20</sup> *Id.* at col. 5, ll. 15-20.

<sup>21</sup> Navarro at col. 4, ll. 64-65.

<sup>22</sup> Cohen at col. 2, ll. 36-38 and col. 5, ll. 5-11.



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Similarly, if the fiber optic was within the electrode device of Cohen additional problems could be caused related to the controlled heating of the vessel. For example, decreasing the amount of material in the bendable section will increase the resistance of the material in this area. Thus greater voltage will be required for the same amount of heating at the tip but a greater amount of heat will be generated at the bendable section. Greater heat at the insulated bendable section is undesirable because the device uses the electrode at the tip to heat the vessel and additional heat at the bendable section could distort the controlled heating process. This could also lead to more insulation being required at the bendable section. More insulation would lead to increased rigidity at the bendable section.

Further as to the controlled heating of the Cohen device within a vessel, the fiber optic device of Navarro would need to be located at the end of the electrode and would decrease the conductive surface area of the electrode that could be in contact with the vessel. Because the Cohen device describes closure of the vessel as being accomplished by intimate contact between the electrode and the vessel wall,<sup>23</sup> the presence of the light in the Cohen arrangement would lead to problems related to sealing the vein because of the decreased amount of the vein that is in contact with the electrode. Incorporating Navarro's light could also lead to other issues such as possible overheating related to the smaller conductive surface area.

For example, the fiber optic could cause the device to get hotter quicker or cause hot spots near where the fiber optic device is located. The presence of the fiber optic could also prevent the device from heating the vessel symmetrically. This could cause the cauterized tissue to have a high impedance, signaling that the device should be moved to a new spot,<sup>24</sup> while not completely closing off the vessel. The feedback control taught by Cohen appears to imply certain conditions such as uniformity of heating at the electrode, as well as uniformity of contact between the electrode and the vessel wall. Both of these conditions would be violated by adding the light of Navarro alongside the device of Cohen.

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<sup>23</sup> *Id.* at col. 3, ll. 44-51.

<sup>24</sup> *Id.* at col. 10, ll. 48-60.

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For at least these reasons, the combination of Cohen and Navarro would render Cohen unsatisfactory for its intended purpose. Therefore the rejection is improper as a *prima facie* case of obviousness has not been established.

c. The Combination Would Not Have A Reasonable Likelihood of Success.

Combining Cohen and Navarro would not have a reasonable likelihood of success primarily because of the non-transmissive material that the Cohen device uses. Cohen teaches that the electrode of the preferred embodiment is made of "type 304 stainless steal."<sup>25</sup> Stainless steal, like other metals, is non-transmissive of light which would pose multiple different problems with the combination of Cohen and Navarro.

If the fiber optic was installed within the Cohen device it is not apparent how the fiber optic would transmit light through the electrode device. The metal would block light from a fiber optic within it such that it would not provide an indication of the location of the device. Any modification to the electrode itself to provide light through the electrode would materially alter the Cohen device which teaches a solid, rounded tip electrode.<sup>26</sup>

Assuming that the fiber optic could be alongside the device, the metal of the electrode would reflect the light from the fiber optic which in turn could misinform the operator about the position of the tip of the device.<sup>27</sup> For example, the tip could reflect the light from the fiber optic even after the tip had entered a junction between two vessels and the user may only be able to tell a difference in the amount of light conveyed to the user after the tip has advanced farther into the second vessel. This would misinform the user as the location of the junction. Additionally, if the device was put in a position such that the electrode was between the light and the operator, here again the non-transmissive material could block the light so that the position would remain unknown.

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<sup>25</sup> *Id.* at col. 4, ll. 61-63.

<sup>26</sup> *Id.* at col. 3, ll. 4-5 and FIG. 2.

<sup>27</sup> *Id.* at col. 5, ll. 33-39 (teaching that the tip is preferably plated with chrome).

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For at least these reasons, the combination of Cohen and Navarro would not have a reasonable likelihood of success and therefore the rejection is improper as a *prima facie* case of obviousness has not been established.

d. The Asserted Combination is Improper Hindsight.

In light of the deficiencies and teachings away set forth above, it appears that the only motivation for combining the references is necessarily the claims and teachings of the present application. This is improper hindsight, because it molds the elements taught in the various cited references into something that will cover the claimed invention, without that alteration being actually present, absent the invention by the Appellants. Indeed, "[o]bviousness can not be established by hindsight combination to produce the claimed invention . . . . [I]t is the prior art itself, and not the appellant's achievement, that must establish the obviousness of the combination."<sup>28</sup>

This can be seen further by analyzing the reasons given in the Final Office Action to make the combination.<sup>29</sup> In order to establish a *prima facie* case of obviousness, the Examiner must provide a reason to combine the references to achieve the specifically recited limitations. It is important for one asserting obviousness "to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."<sup>30</sup>

The assertion that this combination is proper appears to be based solely on: (1) A characterization of Cohen's teaching of "electrical feedback" (even though that feedback has nothing to do with positioning); and (2) Navarro's teaching of "visual guidance or feedback." Based on these asserted teachings of "feedback," it is stated that "[i]t would have therefore been

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<sup>28</sup> *In re Dance*, 160 F.3d 1339 (Fed. Cir. 1998).

<sup>29</sup> Final Office Action at p. 2-3.

<sup>30</sup> *KSR International v. Teleflex*, 127 S.Ct. 1727 at 1741 (2007). See also *In re Deuel*, 51 F.3d 1552 at 1558-59 (Fed. Cir. 1995); *In re Baird*, 16 F.3d 380 at 382-83, 29 U.S.P.Q.2d at 1552 (Fed. Cir. 1994); and *In re Bell*, 991 F.2d 781 at 784, 26 U.S.P.Q.2d at 1531 (Fed. Cir. 1993).

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obvious to one of ordinary skill in the art to use the teaching by Navarro et al. to modify the teaching by Cohen et al. to accommodate a visual feedback system."<sup>31</sup>

Although not acknowledged in the Final Office Action, the method of positioning, cited as visual feedback, of Navarro is integral to the device and method taught therein because the very same optical fiber used for treatment is also used for delivery of a positioning beam of light. As discussed above, the Navarro inventors were well aware of the competing electrode technology at the time of the Navarro invention. Indeed, the Navarro reference goes so far as to explicitly disparage the competing technology in the text of the application itself.<sup>32</sup> Thus, the Navarro inventors considered and rejected what they considered an inferior, competing technology, rather than combining it with laser technology. Therefore, Navarro's approach indicates one example of those skilled in the art rejecting the combination argued to be obvious.

In addition, the types of feedback asserted to be used by Cohen and Navarro differ to such a degree that it would not be obvious to combine them in the simple terms given by the Examiner. Cohen's main focus is monitoring the tissue being energized with an electrode so that overheating does not occur or that the electrode can be stopped from over energizing the tissue. According to Cohen, monitoring to prevent overheating is desirable because "applying rf energy to a blood vein over excessive time periods or at excessively high power can result in arcing and perforation of vein."<sup>33</sup> Thus the feedback that Cohen teaches is the feedback from an electrical sensor to measure electrical changes in the system such as impedance and voltage as a measure of temperature.<sup>34</sup>

In contrast, Navarro teaches the use of laser energy to treat blood vessels, and the feedback, cited in the Final Office Action as taught by Navarro<sup>35</sup> is actually not feedback but rather the visualizing of laser light to position the laser within the vessel.<sup>36</sup> Navarro is not

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<sup>31</sup> Final Office Action at p. 2-3.

<sup>32</sup> Navarro at col. 2, ll. 1-6.

<sup>33</sup> Cohen at col. 2, ll. 30-35, *see also* col. 8, l. 63, col. 9, l. 16 and col. 10, ll. 40-45.

<sup>34</sup> *Id.* at col. 6, ll. 6-10, col. 7, ll. 13-17 and col. 7, l. 58-col.8, l. 9.

<sup>35</sup> Final Office Action at p.2-3.

<sup>36</sup> Navarro at ABSTRACT.

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concerned with electrode overheating of the tissue—and this is natural, because Navarro disparages electrode technology and provides for no temperature feedback mechanism. Indeed, the visualizing of laser light to position the fiber optic of Navarro has nothing to do with electrical feedback related to monitoring the heating of a vessel. Thus the two actions cited as feedback are completely different and are not related to one another. The Final Office Action provides no logical justification for the simplistic rhetorical connection asserting a link between two unrelated actions as types of “feedback.”

For these reasons it appears that the only motivation for combining the references is the claims and teachings of the present application. This is improper hindsight. The Examiner has modified the elements taught in the various cited references into something that will cover the claimed invention, without that alteration being actually present, absent the invention by the Appellants.

In light of all of the above, Appellants submit that the ground of rejection is inadequate. It is respectfully requested that the Board reverse the rejection.

**2. The Obviousness Rejection Regarding Claim 50 is Incorrect.**

**A. The Examiner's Asserted Rejections Regarding Independent Claim 50.**

In Section 3 of the DETAILED ACTION of the Final Office Action, the individual claims are not identified. Likewise, the claim language used by the Examiner to support the rejection of the claims is not identified. Rather, the Final Office Action paraphrases purportedly relevant passages of Cohen and Navarro without establishing their relevance to any particular claims or claim limitations. Thus, the rejection of Claim 50 is combined with the rejection of all of the other claims.

As discussed previously, the Final Office Action asserts that Cohen teaches a “method of electrically treating the sapheno-femoral junction by positioning a device for application of therapeutic energy to the anatomical structure.”<sup>37</sup> Further, the Final Office Action asserts that Navarro also teaches “a method of positioning a catheter proximate to a junction in a hollow

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anatomical structure.”<sup>38</sup> The Final Office Action states that Navarro teaches “introducing a catheter into the hollow anatomical structure and identifying the junction based on feedback from the catheter with the use of light emitted from a fiber optic device.”<sup>39</sup> Next, the Final Office Action asserts that Navarro teaches applying energy to the hollow anatomical structure to reduce the size of the structure.

Additionally, as apparently related to Claim 50, the Final Office Action states that Navarro also teaches the use of a guide wire for introducing the catheter.

**B. Legal Requirements for Establishing a Showing of Obviousness.**

As explained above, the Examiner bears the initial burden to establish and support a *prima facie* case of obviousness.<sup>40</sup> In a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art.<sup>41</sup>

**C. Deficiencies in the Rejection.**

Appellants respectfully submit that the rejections are insufficient because not all of the claim limitations are met by the asserted combinations. For example, in rejecting independent Claim 50, the Final Office Action implies that the Examiner believes that Cohen and Navarro teach all of the claim limitations of Claim 50. However, the Final Office Action does not specifically indicate where these limitations are found in either Cohen or Navarro.

The Final Office Action, for example, never addresses the following portion of Claim 50: “introducing a guide wire having a hook-shaped tip into the hollow anatomical structure” (emphasis added). Nor does the Final Office Action discuss this portion of Claim 50: “hooking the hook-shaped tip of the guide wire to an ostium of a junction within the hollow anatomical structure” (emphasis added). Instead of addressing the language of the claim, the Final Office Action merely asserts:

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<sup>37</sup> Final Office Action at p. 2.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* (citation omitted).

<sup>40</sup> See *In re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. 143 (C.C.P.A. 1976).

<sup>41</sup> See *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

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*The reference [Navarro] also teaches the step of introducing the catheter over a guide wire with a tip located at the distal end of the guide wire or located at the working end of the catheter wherein the guide wire transverses a lumen in the catheter and the tip is adaptable to engage the junction of the anatomical structure while the catheter travels over the guide wire to the junction where it "wedges" against the junction (col. 4 lines 39-43).<sup>42</sup>*

It is difficult to determine if this passage from the Final Office Action is referring to independent Claim 50, but even if this passage is an attempt to demonstrate that Claim 50 is obvious, the attempt is not successful. This is because, for example, the passage from the Final Office Action does not assert that the limitations referenced above are taught or suggested by Navarro. Indeed, these limitations are not taught or suggested by Navarro. The section of Navarro cited in the Final Office Action states, in its entirety:

*As shown in FIGS. 3A and 3B, angiocatheter 38, or a device of similar function, is placed percutaneously into greater saphenous vein 30. To aid in the placement of catheter 38, ultrasound imaging, or a similar function device may be used.<sup>43</sup>*

Neither this section nor the figures referenced therein make reference to any type of a guide wire, and they certainly do not teach the limitations of Claim 50. In fact, as one can see from the passage above, the cited section of Navarro recommends that a different method—namely, an ultrasound imager—be used to aid in the placement of the angiocatheter.

The Final Office Action makes no assertions related to Cohen and any type of a guide wire. This is appropriate, as Cohen provides no teachings related to how the probe of Cohen is positioned within a hollow anatomical structure. Thus, neither Cohen nor Navarro teach "hooking the hook-shaped tip of the guide wire to an ostium of a junction within the hollow anatomical structure," as recited in Claim 50.

The claim rejection additionally fails as it is unknown where support is derived for many of the statements in the Final Office Action. For example, the following statements appear to be unsupported: "the tip [of the guide wire] is adaptable to engage the junction"; and "the catheter

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<sup>42</sup> Final Office Action at p. 3.

<sup>43</sup> Navarro at col. 4, ll. 39-43.

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travels over the guide wire to the junction where it 'wedges' against the junction." Neither of these statements is supported by the cited section of Navarro, and neither appears to be drawn from any other passage of Navarro. However, even if these statements were drawn from the reference, they would not be sufficient to support a 35 U.S.C. §103(a) rejection of Claim 50 because they do not teach or suggest the limitations of Claim 50.

The Final Office Action at page 3 has the word "wedges" in quotes, implying that either Navarro uses the term "wedges" in its disclosure, or that the term "wedges" is a claim limitation. Neither proposition is true. A search of the Navarro disclosure confirms that the word "wedges" is not used therein. The cited section also does not disclose a method that would involve "wedging" or something similar thereto. The claims of the above-referenced application likewise do not recite "wedges" or "wedging."

The Final Office Action concludes the discussion of the guide wire by stating that the tip of the guide wire is rounded. Thus, the Final Office Action acknowledges that Navarro does not disclose a "hooked" tip but asserts instead that it teaches a rounded tip on the guide wire. The Final Office Action provides no discussion concerning how a guide wire with a rounded tip would lead one skilled in the art to the limitations discussed above in Claim 50.

For at least the reasons discussed above, Cohen and Navarro, alone or in combination, do not disclose or suggest all of the limitations of Claim 50. Accordingly, it is respectfully requested that the rejection be reversed.

### 3. Dependent Claims 2-7, 16, 21, 51-53, 70-72, 75-77, 79-88 and 90-94

The obviousness rejection of dependent claims 2-7, 16, 21, 70-72 and 75-77 is improper in view of their respective dependencies from independent Claim 1. The obviousness rejection of dependent Claims 51-53 is improper in view of their respective dependencies from independent Claim 50. The obviousness rejection of dependent claims 79-88 is improper in view of their respective dependencies from independent Claim 78. The obviousness rejection of dependent claims 90-94 is improper in view of their respective dependencies from independent Claim 89. In addition, the obviousness rejection of these claims is improper for the additional



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reasons provided below for representative claims. By declining to present arguments in favor of certain dependent claims, Appellants do not imply an agreement with the assertion's regarding such claims in the Final Office Action.

**Dependent Claim 5**

The rejection of Claim 5 is additionally improper because neither Navarro nor Cohen teach or suggest "the step of measuring the length of the fiber optic device introduced into the patient until the attribute of the light changes," as recited in Claim 5. The Final Office Action does not address this feature of the Claims. In fact, neither Navarro nor Cohen contains any teaching or suggestion relating to measuring the length of the fiber optic or any other device. Thus, the rejection lacks any basis and should be reversed.

**Dependent Claim 6**

The rejection of Claim 6 is additionally improper because neither Navarro nor Cohen teach or suggest "the step of removing the fiber optic device after the step of measuring," as recited in Claim 6. The Final Office Action does not address this feature of the Claims. As mentioned above, Navarro and Cohen do not teach or suggest the step of measuring the fiber optic device; therefore they also do not teach or suggest removing the fiber optic device after the step of measuring. Moreover, Navarro teaches away from removing the fiber optic device because that device remains in place during the treatment. Appellants request that the rejection be reversed.

**Dependent Claim 7**

The rejection of Claim 7 is additionally improper because neither Navarro nor Cohen teach or suggest "wherein the step of positioning further includes the step of inserting the treatment device for the same length as measured in the step of measuring the length of the fiber optic device," as recited in Claim 7. The Final Office Action does not address this feature of the Claims. As mentioned above, Navarro and Cohen do not teach or suggest the step of measuring the fiber optic device; therefore they also do not teach or suggest inserting the treatment device for the same length as measured in the step of measuring the length of the fiber optic device. Appellants request that the rejection be reversed.

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#### **Dependent Claim 16**

The rejection of Claim 16 is additionally improper because neither Navarro nor Cohen teach or suggest "wherein the step of introducing said treatment device comprises introducing said treatment device over a guidewire with a hook shaped tip located at the distal end of a guide wire, and the hook shaped tip is adaptable to engage the junction of the hollow anatomical structure while the treatment device travels over the guidewire to the junction," as recited in Claim 16. As more fully discussed above in regard to Claim 50, neither Navarro nor Cohen teach or suggest a guidewire with a hook shaped tip. Therefore these references do not make obvious the step of introducing a treatment device over such a guidewire. Appellants request that the Board reverse the rejection.

#### **Dependent Claim 52**

The rejection of Claim 52 is additionally improper because neither Navarro nor Cohen teach or suggest "wherein the step of positioning further includes the step of stopping the advancement of the catheter by a mechanical stop located proximal to the hook shaped tip of the guide wire," as recited in Claim 52. The Final Office Action does not address this feature of the claims. As discussed more fully above with regard to Claim 50, neither Navarro nor Cohen teach or suggest a guide wire. In addition, neither reference teaches or suggests a guide wire with a mechanical stop. For this reason, Appellants request that the rejection be reversed.

#### **Dependent Claim 53**

The rejection of Claim 53 is additionally improper because neither Navarro nor Cohen teach or suggest "the step of measuring the length of the guide wire introduced into the patient in the step of hooking," as recited in Claim 53. The Final Office Action does not address this feature of the claims. As previously discussed in Claim 5, neither Navarro nor Cohen contains any teaching or suggestion relating to measuring the length of any device, this includes measuring the length of the guide wire. Thus, the rejection lacks any basis and should be reversed.

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### VIII. CONCLUSION

For the reasons explained above, Appellants respectfully submit that the rejections of Claims 1-7, 16, 21, 50-53, 70-72 and 75-94 are improper and should be reversed.

Please charge any additional fees that may be required now or in the future to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 21, 2009

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#### **APPENDIX I. - CLAIMS**

1. A method of positioning an elongate treatment device proximate to a junction in a hollow anatomical structure of a patient, the method comprising the steps of:

introducing the treatment device into the hollow anatomical structure, the treatment device comprising an elongate shaft and an electrically driven energy application device at a working end of the shaft;

identifying the junction in the hollow anatomical structure by emitting light via a fiber optic device positioned in the hollow anatomical structure;

positioning the working end of the treatment device proximate the junction identified in the step of identifying;

applying energy to the hollow anatomical structure proximate the junction via the energy application device so as to lead to a reduced diameter for the hollow anatomical structure.

2. The method of claim 1 wherein the junction in the step of identifying is the sapheno-femoral junction.

3. The method of claim 1 wherein an attribute of the light changes upon the fiber optic device reaching the junction of the hollow anatomical structure.

4. The method of claim 1 wherein the step of introducing the treatment device further includes the step of introducing the treatment device over the fiber optic device.

5. The method of claim 3 further including the step of measuring the length of the fiber optic device introduced into the patient until the attribute of the light changes.

6. The method of claim 5 further including the step of removing the fiber optic device after the step of measuring.

7. The method of claim 5 wherein the step of positioning further includes the step of inserting the treatment device for the same length as measured in the step of measuring the length of the fiber optic device.

8-15. (Cancelled)

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16. The method of claim 1 wherein introducing said treatment device comprises introducing said treatment device over a guidewire with a hook shaped tip located at the distal end of a guide wire, and the hook shaped tip is adaptable to engage the junction of the hollow anatomical structure while the treatment device travels over the guidewire to the junction.

17-20. (Cancelled)

21. The method of claim 1 wherein the step of introducing the treatment device further includes the step of introducing the treatment device over a guide wire.

22-49. (Cancelled)

50. A method of positioning a catheter within a hollow anatomical structure, the method comprising the steps of:

introducing a guide wire having a hook-shaped tip into the hollow anatomical structure;

hooking the hook-shaped tip of the guide wire to an ostium of a junction within the hollow anatomical structure;

introducing a catheter having a working end into the hollow anatomical structure over the guide wire;

positioning the working end of the catheter proximate the junction identified in the step of hooking; and

applying energy to the hollow anatomical structure at the treatment site via an energy application device at the working end of the catheter to heat but not cut the hollow anatomical structure until the hollow anatomical structure durably assumes a smaller size such that the reduced diameter of the hollow anatomical structure effectively ligates the hollow anatomical structure.

51. The method of claim 50 wherein the junction in the step of hooking is the sapheno-femoral junction.

52. The method of claim 50 wherein the step of positioning further includes the step of stopping the advancement of the catheter by a mechanical stop located proximal to the hook shaped tip of the guide wire.

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53. The method of claim 50 further comprising the step of measuring the length of the guide wire introduced into the patient in the step of hooking.

54-69. (Cancelled)

70. The method of claim 1 wherein the step of applying energy heats but does not cut the hollow anatomical structure wherein the reduced diameter of the hollow anatomical structure results in occlusion of the hollow anatomical structure.

71. The method of claim 1, wherein applying energy to the hollow anatomical structure effectively ligates the hollow anatomical structure.

72. The method of claim 1 wherein the reduced diameter of the hollow anatomical structure results in occlusion of the hollow anatomical structure.

73-74. (Cancelled)

75. The method of claim 1, wherein the energy application device comprises a plurality of electrodes.

76. The method of claim 1, wherein the energy application device comprises a resistive coil.

77. The method of claim 1, wherein the fiber optic device is an integrated part of the treatment device.

78. A method of positioning a device for application of therapeutic energy to a target portion of a hollow anatomical structure, the method comprising:

emitting light from within a hollow anatomical structure;

monitoring the light from outside the hollow anatomical structure to determine information about the location of a junction between a target portion and a region adjacent the hollow anatomical structure;

introducing a catheter having a working end into the hollow anatomical structure, the catheter having a therapeutic energy device at the working end, the therapeutic energy device distinct from the light;

using the information to position the therapeutic energy device near the junction;

and

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applying energy from the therapeutic energy device to the target portion.

79. The method of claim 78, wherein the therapeutic energy device is positioned separately from the light.

80. The method of claim 78, further comprising the step of expanding the therapeutic energy device to provide physical engagement with the hollow anatomical structure.

81. The method of claim 80, wherein the step of expanding occurs after the step of using the information to position the therapeutic energy device.

82. The method of claim 78, wherein the hollow anatomical structure is a blood vessel.

83. The method of claim 78, wherein the hollow anatomical structure is the saphenous vein, the sapheno-femoral junction, and the femoral vein.

84. The method of claim 78, wherein the target portion is the saphenous vein.

85. The method of claim 78, wherein the light is a fiber optic device.

86. The method of claim 85, wherein the fiber optic device is configured to emit light in a radial fashion.

87. The method of claim 78, wherein the therapeutic energy device is an electrode device.

88. The method of claim 78, wherein the catheter comprises the light.

89. A method of positioning a device for application of therapeutic energy to a target portion of a hollow anatomical structure, the method comprising:

emitting visual feedback light from a visual feedback device positioned within a hollow anatomical structure;

monitoring the visual feedback light from outside the hollow anatomical structure to determine information about the location of a junction between a target portion and a non-target portion of the hollow anatomical structure;

introducing, into the hollow anatomical structure, a catheter having a therapeutic energy device at the catheter's working end, the therapeutic energy device distinct from the visual feedback device;

using the information to position the therapeutic energy device near the junction and prevent the therapeutic energy device from extending into the non-target portion; and

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applying energy from the therapeutic energy device to the target portion.

90. The method of claim 89, wherein therapeutic energy device is positioned separately from the visual feedback light.

91. The method of claim 89, wherein the target portion is the saphenous vein.

92. The method of claim 89, wherein the non-target portion is the femoral vein.

93. The method of claim 89, wherein the visual feedback device is configured to emit light in a radial fashion.

94. The method of claim 89, wherein the catheter comprises the visual feedback light.



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## **APPENDIX II. - EVIDENCE**

None

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### **APPENDIX III. - RELATED PROCEEDINGS**

None